510(K) SUMMARY

Name of Firm

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DEC 22 2009

Official Correspondent

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Manager of Regulatory Affairs and Quality Assurance
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Establishment Number

3005129649

Device Name

Legally Marketed Trade Name: PATHWAY ACIF
Common Name: Intervertebral fusion device with bone graft, cervical/Vertebral Body Replacement
Device Classification: Class II
Regulation Number: 21 CFR 888.3060, 21 CFR 888.3080
Device Product Codes: MQP, ODP

Predicate Devices

LDR Spine MC+ (K043479), Zimmer Spine BAK/C Cervical Interbody Fusion Device (P980048), and X-Spine Calix ™Spinal Implant (K083637)

Device Description

The PATHWAY ACIF is a cervical interbody fusion device made from PEEK OPTIMA LT-1 (Polyetheretherketone). The device contains tantalum pins used to serve as identification markers for the end user of the device to determine the location of the implant both intra-operatively and post-operatively.

The device is trapezoidal in nature and is provided in various heights ranging from 5 mm to 12 mm and a width of 15 mm, and 13 mm in length. This device contains a central cavity which is to be packed with autograft. This device is provided in various degrees of lordosis (0 Degree and 7 Degree). The superior and inferior surfaces have serrated teeth to help resist implant migration/displacement.

The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

The product is provided clean and "non-sterile".

Indications for Use

The PATHWAY ACIF, when used as an intervertebral body fusion device, is intended is for spinal fusion procedures at one level (C2-T1) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. Patients should receive 6 weeks of non-operative treatment prior to treatment with the PATHWAY ACIF intervertebral body fusion device.

When used as a vertebral body replacement, the PATHWAY ACIF is intended for use in the thoracic and/or throcolumbar spine (TI-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e. partial or total vertebrectomy procedures) due to tumor or trauma (i.e. fracture). The PATHWAY ACIF, when used as a vertebral body replacement, can be packed with autograft.

For all indications, the device is intended to be used with supplemental fixation systems that have been cleared for use in cervical, thoracic, or lumbar spine (posterior pedicle screw systems, anterior plate systems, and anterior screw and rod systems).

Materials

The PATHWAY ACIF is made from PEEK OPTIMA LT-1 (Polyetheretherketone) and contains tantalum markers (ASTM F560).

Performance Data

The PATHWAY ACIF device was tested in accordance with ASTM F2267-04 *"Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Devices Under Static Axial Compression"*, and ASTM F2077-03 *"Test Method For Intervertebral Body Fusion Devices"*. The data are located in Section 19 of this submission, "Bench Testing". The data demonstrate that the device is capable of performing in accordance with its intended use.

Substantial Equivalence Statement

The PATHWAY ACIF is equivalent to the previously cleared systems, as they utilize the same principle of operation, and has similar indications for use as the predicates, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 22 2009

Custom Spine, Inc.
% Mr. Saad Attiyah
Manager of Regulatory Affairs
and Quality Assurance
1140 Parsippany Boulevard, Suite 201
Parsippany, New Jersey 07054

Re: K092904
Trade Name: Pathway ACIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MQP
Dated: November 24, 2009
Received: November 27, 2009

Dear Mr. Attiyah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

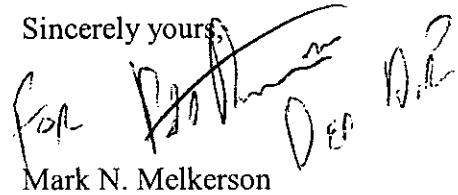
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K092904

When used as an intervertebral body fusion device, the Custom Spine PATHWAY ACIF is intended for spinal fusion procedures at one level (C2-T1) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. Patients should receive 6 weeks of non-operative treatment prior to treatment with the Custom Spine ACIF.

When used as a vertebral body replacement, the Custom Spine PATHWAY ACIF is intended for use in the thoracic and/or throcolumbar spine (TI-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e. partial or total vertebrectomy procedures) due to tumor or trauma (i.e. fracture). The PATHWAY ACIF, when used as a vertebral body replacement, can be packed with autograft.

For all indications, the device is intended to be used with supplemental fixation systems that have been cleared for use in cervical, thoracic, or lumbar spine (posterior pedicle screw systems, anterior plate systems, and anterior screw and rod systems).

Prescription Use __X__ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092904